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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/632,706 | 08/01/2003 | James D. Marks | 407T-895120US | 5306 |
| 22798 | 7590 | 12/23/2005 | EXAMINER | |
| QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501 | | | MINNIFIELD, NITA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/632,706 | Applicant(s) MARKS ET AL. | |
| | Examiner N. M. Minnifield | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-118 is/are pending in the application.
- 4a) Of the above claim(s) 2-7,9-16,58-96,98-103 105-112 and 118 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8,17-57,97,104 and 113-117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2-7,9-16,58-96,98-103,105-112 and 118 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/18/05; 10/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I, claims 1, 8, 17-57, 97, 104 and 113-117, clone huC25 and SEQ ID NO: 86 + 87 + 88 + 89 + 126 + 127 + 128 (HV) and SEQ ID NO: 156 + 157 + 158 + 159 + 196 + 197 + 198 (VL), in the reply filed on September 6, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 2-7, 9-16, 58-96, 98-103, 105-112 and 118 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 6, 2005.

3. Claims 97, 104 and 113-117 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of "plurality"; it is not clear what Applicants intend. What are the metes and bounds of "plurality"? Claims 97 and 104 lack

antecedent basis in the recitation of “an antibody”, see line 4 of claim 97. Is this the same antibody as in line 1?

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 8, 24, 27-57 97 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Amersdorfer et al (Infection and Immunity, Sept. 1997, 65/9:3743-3752).

Amersdorfer et al discloses an isolated single-chain Fv (scFv) anti-botulinum neurotoxin type A (BoNT/A) antibody capable of neutralizing botulinum neurotoxin type A. The antibody of Amersdorfer et al specifically binds to an epitope of botulinum neurotoxin type A (BoNT/A) binding domain (Hc) (Abstract and Materials and Methods). The prior art anticipates the claimed invention.

6. Claims 1, 8, 24, 27-57 97 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (Infection and Immunity, May 1997, 65/5:1626-1630).

Chen et al disclose an isolated single chain antibody and that these antibodies bind to BoNT/A and neutralizing antibodies against botulism poisoning (abstract; p. 1627; p. 1626; p. 1630). The prior art anticipates the claimed invention.

7. Claims 1, 8, 17-22, 29-46, 50-57, 97, 104 and 113-117 are rejected under 35 U.S.C. 102(b) as being anticipated by Amersdorfer et al (Vaccine 22 February 2002, 20:1640-1648) or Mullaney et al (Infection and Immunity, Oct. 2001, 69/10:6511-6514).

Amersdorfer et al, for example, discloses an isolated single chain antibody against botulinum neurotoxin type A (abstract; p. 1641, left column; materials and methods, p. 1641). These antibodies bind to and neutralize BoNT/A (p. 1641, left column; p. 1647, right column). The prior art anticipates the claimed invention.

8. Claims 1, 8, 17-22, 29-43, 50-57, 97, 104 and 113-117 are rejected under 35 U.S.C. 102(b) as being anticipated by Bavari et al (Vaccine 22 February 2002, 20:1640-1648).

Bavari et al discloses isolated antibodies that neutralize BoNT/A and that mAb against BoNT/A were isolated and cloned (abstract; p. 1851, left column; materials and methods; p. 1852, left column). The prior art


9. No claims are allowed.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
December 13, 2005